

## Food and Drug Administration, HHS

## § 884.3

884.4120 Gynecologic electrocautery and accessories.  
884.4150 Bipolar endoscopic coagulator-cutter and accessories.  
884.4160 Unipolar endoscopic coagulator-cutter and accessories.  
884.4250 Expandable cervical dilator.  
884.4260 Hygroscopic Laminaria cervical dilator.  
884.4270 Vibratory cervical dilators.  
884.4340 Fetal vacuum extractor.  
884.4400 Obstetric forceps.  
884.4500 Obstetric fetal destructive instrument.  
884.4520 Obstetric-gynecologic general manual instrument.  
884.4530 Obstetric-gynecologic specialized manual instrument.  
884.4550 Gynecologic surgical laser.  
884.4900 Obstetric table and accessories.

### Subpart F—Obstetrical and Gynecological Therapeutic Devices

884.5050 Metreurynter-balloon abortion system.  
884.5070 Vacuum abortion system.  
884.5100 Obstetric anesthesia set.  
884.5150 Nonpowered breast pump.  
884.5160 Powered breast pump.  
884.5225 Abdominal decompression chamber.  
884.5250 Cervical cap.  
884.5300 Condom.  
884.5310 Condom with spermicidal lubricant.  
884.5320 Glans sheath.  
884.5330 Female condom.  
884.5350 Contraceptive diaphragm and accessories.  
884.5360 Contraceptive intrauterine device (IUD) and introducer.  
884.5380 Contraceptive tubal occlusion device (TOD) and introducer.  
884.5390 Perineal heater.  
884.5400 Menstrual cup.  
884.5425 Scented or scented deodorized menstrual pad.  
884.5435 Unscented menstrual pad.  
884.5460 Scented or scented deodorized menstrual tampon.  
884.5470 Unscented menstrual tampon.  
884.5900 Therapeutic vaginal douche apparatus.  
884.5920 Vaginal insufflator.  
884.5940 Powered vaginal muscle stimulator for therapeutic use.  
884.5960 Genital vibrator for therapeutic use.  
884.5970 Clitoral engorgement device.

### Subpart G—Assisted Reproduction Devices

884.6100 Assisted reproduction needles.  
884.6110 Assisted reproduction catheters.  
884.6120 Assisted reproduction accessories.  
884.6130 Assisted reproduction microtools.  
884.6140 Assisted reproduction micropipette fabrication instruments.

884.6150 Assisted reproduction micro-manipulators and microinjectors.  
884.6160 Assisted reproduction labware.  
884.6170 Assisted reproduction water and water purification systems.  
884.6180 Reproductive media and supplements.  
884.6190 Assisted reproductive microscopes and microscope accessories.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 45 FR 12684-12720, Feb. 26, 1980, unless otherwise noted.

## Subpart A—General Provisions

### § 884.1 Scope.

(a) This part sets forth the classification of obstetrical and gynecological devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a obstetrical and gynecological device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[52 FR 17740, May 11, 1987]

### § 884.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving